

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION**

GAYATHRI MURTHY,)	
)	
Plaintiff,)	
)	Case No. 4:11-cv-00105-KPE
v.)	
)	Hon. Judge Keith P. Ellison
ABBOTT LABORATORIES,)	
)	
Defendant.)	

**DEFENDANT ABBOTT LABORATORIES’ UNOPPOSED MOTION
FOR LEAVE TO FILE SUPPLEMENTAL AUTHORITY**

Pursuant to Local Rule 7.8, Defendant Abbott Laboratories (“Abbott”) respectfully requests that the Court grant it leave to submit the following supplemental authority in support of its motion for certification for interlocutory appeal of the Court’s November 8, 2011 Memorandum and Order (Dkt. 42): *Lofton v. McNeil Consumer & Specialty Pharm.*, No. 10-10956 (5th Cir. Feb. 22, 2012) (attached hereto as Ex. 1). In *Lofton*, the Fifth Circuit conclusively held that the “fraud-on-the-FDA” exception to the Section 82.007 presumption against liability is preempted by the Food, Drug and Cosmetic Act and thus unavailable under *Buckman Co. v. Pls.’ Legal Comm.*, 531 U.S. 341 (2001), and its progeny.

This new clarification is critical to Abbott’s motion to dismiss. As this Court recognized in its initial consideration of Abbott’s motion, “[w]hether the exception articulated [in] § 82.007(b)(1) is preempted is an issue that has not yet been decided by the Supreme Court or the Fifth Circuit.” (Dkt. 39 at 21) Thus, although Abbott urged the Court to find that the exception was preempted (*see* Dkt. 17 at 15 n.9; Dkt. 26 at 3-4), this Court cautiously observed that “guidance from the Fifth Circuit” would be appropriate because there was no clear rule and

thus declined to “determine at this stage whether § 82.007(b)(1) is preempted.” (Dkt. 39 at 24 n.8, 26-27)

The *Lofton* opinion now provides this “guidance,” which is dispositive on plaintiffs’ product liability claims. The Fifth Circuit expressly held that Section 82.007(b)(1)’s fraud-on-the-FDA exception “is preempted unless the FDA itself has found fraud.” *See Lofton*, slip op. at 16. It reasoned that “the threat of imposing state liability on a drug manufacturer for defrauding the FDA intrudes on the competency of the FDA and its relationship with regulated entities.” *Id.* at 15. By removing the only exception to Section 82.007 that plaintiff has identified as potentially applicable in this case (*see* Dkt. 24 at 10-11),¹ the *Lofton* decision has confirmed that plaintiffs’ products liability claims are barred by Section 82.007 and thus ripe for dismissal. Accordingly, the Court should dismiss plaintiff’s strict liability, negligence, and breach of warranty counts.²

¹ Plaintiff’s counsel has not—and cannot consistent with counsel’s Rule 11 obligations—claim that any of the four remaining statutory exceptions are applicable here: defendant’s sale or prescription of the product after an FDA order to remove the product from the market or withdrawal of FDA approval (§ 82.007(b)(2)); defendant’s promotion for an indication not approved by the FDA (§ 82.007(b)(4)); defendant’s prescription for an indication not approved by the FDA (§ 82.007(b)(4)); or defendant’s engaging in conduct that would constitute a violation of 18 U.S.C. § 201 (§ 82.007(b)(5)).

² The Court has already denied three of plaintiff’s remaining arguments opposing application of the Section 82.007 bar: (1) Section 82.007 does not apply to clinical trials; (2) Section 82.007 does not apply where not all of the information provided to plaintiff was FDA approved; and (3) the fact that the FDA subsequently mandated stricter warnings rebuts the statutory presumption. (Dkt. 39 at 22-24) Plaintiff’s final argument—that if Section 82.007(b)(1) is preempted, then the entirety of Section 82.007 would be constitutionally invalid because the remaining sections are not severable—should be rejected for the reasons set forth in *Abbott’s* reply. (Dkt. 26 at 3 n.2)

CONCLUSION

For the foregoing reasons, Abbott respectfully requests that the Court grant Abbott leave to file *Lofton* as a supplemental authority, amend its November 8, 2011 Order, and dismiss plaintiff's strict liability, negligence, and breach of warranty claims.³

DATED: March 1, 2012

Respectfully submitted,

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³ To the extent plaintiff purports to assert additional theories of negligence—for example, “Abbott’s [negligent] testing of Humira and its negligent handling of adverse events” (Dkt. 24 at 8; Dkt. 39 at 28)—such theories should likewise be dismissed under Section 82.007 because they are simply a type of failure-to-warn claim. *See, e.g., Dow Agrosciences LLC v. Bates*, 332 F.3d 323, 333 (5th Cir. 2003) (“a negligent testing claim is, as a matter of Texas law, a variation of an action for failure to warn”), *vacated on other grounds, Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005); *Skotak v. Tenneco Resins, Inc.*, 953 F.2d 909, 912 n.5 (5th Cir. 1992) (plaintiffs’ “negligence claims, such as the alleged failure to adequately test Thorotrast, are subsumed within” a failure-to-warn claim); *Am. Tobacco Co., Inc. v. Grinnell*, 951 S.W.2d 420, 437 (Tex. 1997) (“[T]he negligent testing claim is predicated on [defendant’s] duty to test and ascertain the dangers inherent in its products about which it must warn consumers. . . . [T]he negligent testing claim [is] inextricably intertwined with [plaintiffs’] negligent failure to warn claim”); *Mensing v. Wyeth, Inc.*, 562 F. Supp. 2d 1056, 1058 (D. Minn. 2008) (considering plaintiffs’ negligent post-marketing safety surveillance claims as failure-to-warn claims because “at the core of all of Plaintiff’s claims is the basic assertion that [defendants] failed to adequately warn about the association between long-term ingestion of MCP and movement disorders”), *rev’d in part on other grounds*, 588 F.3d 603 (8th Cir. 2009), *rev’d and remanded on other grounds, PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567 (2011).

CERTIFICATE OF SERVICE

I hereby certify that on March 1, 2012, I electronically filed the foregoing DEFENDANT ABBOTT LABORATORIES' UNOPPOSED MOTION FOR LEAVE TO FILE SUPPLEMENTAL AUTHORITY with the clerk of court for the U.S. District Court, Southern District of Texas, using the electronic case filing system of the court. The electronic case filing system sent a "Notice of Electronic Filing" to the following attorneys of record who are known "Filing Users":

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CERTIFICATE OF CONFERENCE

I hereby certify that I, Traci L. Shafroth, of KIRKLAND & ELLIS LLP, counsel for defendant Abbott Laboratories, conferred with Fred Shepherd of PERDUE KIDD & VICKERY, counsel for plaintiff, on March 1, 2012. Plaintiff's counsel indicated that plaintiff does not oppose Abbott's filing of its Motion for Leave to File Supplemental Authority.

DATED: March 1, 2012

/s/ Traci L. Shafroth
Traci L. Shafroth